

In the Claims:

Please amend the Claims as follows (the changes in these Claims are shown with ~~strikethrough~~ for deleted matter and underlines for added matter). A complete listing of the claims proper claim identifiers is set forth below.

1. (**Currently Amended**) A solid drug formulation comprising granulates containing 30 to 90 mg of ospemifene or a pharmaceutically acceptable salt thereof, in combination with one or more intra-granular excipients, wherein at least one intra-granular excipient is a disintegrant in the range of 0.1 to 10 weight-% of the granulates and wherein at least 80% of the formulation is dissolved within 30 minutes after subjecting said formulation to dissolution testing at pH 9.8 according to the USP 24 paddle method.

2. (**Currently Amended**) The drug formulation according to claim 1 wherein the active ingredient is ospemifene is a free base.

3. (**Previously Presented**) The drug formulation according to claim 1 wherein the disintegrant is selected from the group consisting of povidone, crospovidone, carboxymethyl-cellulose, methylcellulose, alginic acid, croscarmellose sodium, sodium starch glycolate, starch, formaldehyde-casein and combinations thereof.

4. (**Original**) The drug formulation according to claim 1 wherein at least one intra-granular excipient is a diluent.

5. (**Original**) The drug formulation according to claim 1 wherein at least one intra-granular excipient is a binder.

6. (**Previously Presented**) The drug formulation according to claim 1 wherein the intra-granular excipient is

- a combination of at least one diluent and at least one disintegrant;
- a combination of at least one disintegrant and at least one binder; or

- a combination of at least one diluent, at least one disintegrant and at least one binder.

Claim 7 (Canceled).

8. **(Original)** The drug formulation according to claim 4 wherein the diluent is selected from the group consisting of maltose, maltodextrin, lactose, fructose, dextrin, microcrystalline cellulose, pregelatinized starch, sorbitol, sucrose, silicified microcrystalline cellulose, powdered cellulose, dextrates, mannitol, calcium phosphate and combinations thereof.

9. **(Original)** The drug formulation according to claim 5 wherein the binder is selected from a group consisting of acacia, dextrin, starch, povidone, carboxymethylcellulose, guar gum, glucose, hydroxypropyl methylcellulose, methylcellulose, polymethacrylates, maltodextrin, hydroxyethyl cellulose and combinations thereof.

Claim 10 (Canceled).

11. **(Original)** The drug formulation according to claim 1 wherein the granulates are made by wet granulation.

Claims 12 – 23 (Canceled).

24. **(Previously Presented)** The drug formulation according to claim 2 wherein the disintegrant is selected from the group consisting of povidone, crospovidone, carboxymethyl-cellulose, methylcellulose, alginic acid, croscarmellose sodium, sodium starch glycolate, starch, formaldehyde-casein and combinations thereof.

Claims 25 and 26 (Canceled).

27. **(Previously Presented)** The drug formulation according to claim 2 wherein the intra-granular excipient is

- a combination at least one diluent and at least one disintegrant;
- a combination of at least one disintegrant and at least one binder; or
- a combination of at least one diluent, at least one disintegrant and at least one binder.

Claim 28 (**Canceled**).

29. (**Previously Presented**) The drug formulation according to claim 27 wherein the diluent is selected from the group consisting of maltose, maltodextrin, lactose, fructose, dextrin, microcrystalline cellulose, pregelatinized starch, sorbitol, sucrose, silicified microcrystalline cellulose, powdered cellulose, dextrates, mannitol, calcium phosphate and combinations thereof.

30. (**Previously Presented**) The drug formulation according to claim 29 wherein the binder is selected from a group consisting of acacia, dextrin, starch, povidone, carboxymethylcellulose, guar gum, glucose, hydroxypropyl methylcellulose, methylcellulose, polymethacrylates, maltodextrin, hydroxyethyl cellulose and combinations thereof.

Claims 31 and 32 (**Canceled**).

33. (**Previously Presented**) A solid drug formulation comprising granulates containing 30 to 90 mg of ospemifene or a pharmaceutically acceptable salt thereof in combination with one or more excipients selected from pregelatinized starch, maize starch, povidone, sodium starch glycolate, and magnesium stearate, wherein at least 80% of the formulation is dissolved within 30 minutes after subjecting said formulation to dissolution testing at pH 9.8 according to the USP 24 paddle method.

34. (**Currently amended**) A solid drug formulation according to claim 33 comprising granulates of the following ingredients:

Names of the ingredients	Quantity (%) GRANULATION	Quantity (%) DIRECT COMPRESSION	Function
Ospemifene	30	30	Active
Pregelatinized starch	38	38	Diluent
Maize starch	25	25	Diluent
Povidone	2	2	Binder
Sodium starch glycolate	4	4	Disintegrant
Magnesium stearate	1	1	Lubricant
Water, purified*	25	-	Solvent

* Evaporates during the manufacturing process

Names of the ingredients	Quantity (%) Granulation	Function
Ospemifene	30	Active
Pregelatinized starch	38	Diluent
Maize starch	25	Diluent
Povidone	2	Binder
Sodium starch glycolate	4	Disintegrant
Magnesium stearate	1	Lubricant
Water, purified*	25	Solvent

*Evaporates during the manufacturing process

wherein at least 80% of the formulation is dissolved within 30 minutes after subjecting said formulation to dissolution testing at pH 9.8 according to the USP 24 paddle method.

Claims 35 – 39 (**Canceled**).

40. (**New**) The drug formulation according to claim 1 wherein the disintegrant is sodium starch glycolate.

41. (**New**) The drug formulation according to claim 2 wherein the disintegrant is sodium starch glycolate.